



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,717	02/20/2004	Steve G. Baker	2234-3-3	5604

996 7590 09/13/2006

GRAYBEAL, JACKSON, HALEY LLP
155 - 108TH AVENUE NE
SUITE 350
BELLEVUE, WA 98004-5901

EXAMINER

POUS, NATALIE R

ART UNIT PAPER NUMBER

3731

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/783,717

Applicant(s)

BAKER ET AL.

Examiner

Natalie Pous

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 29-40, 44-76, 78-85 and 95-114 is/are rejected.
- 7) ☒ Claim(s) 28, 41-43, 77 and 86-94 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/24/05, 9/27/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: IDS: 7/19/04, 7/15/04.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45 and 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 recites the limitation "the metal" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 99 recites the limitation "the tissue" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 14, 47, 48, 50-54, 63-67 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Hart (US 5626614).

Regarding Claim 1, Hart teaches a fastener for use in a mammalian body, comprising: a first member (12); a second member (16), the first and second members

Art Unit: 3731

having first and second ends; and a connecting member (14) fixed to each of the first and second members intermediate the first and second ends and extending between the first and second members, the first and second members being separated by the connecting member (fig. 4), and one of the first and second members (12) having a longitudinal axis, a through channel (83) along the axis arranged to be slidably received on a tissue piercing deployment wire (54), and an elongated slot (103) communicating with the through channel and dimensioned to receive the tissue piercing deployment wire (fig. 7).

Regarding Claim 2, Hart teaches the fastener of claim 1 wherein one end of the one of the first and second members (12) further includes a pointed tip (101).

Regarding Claim 3, Hart teaches the fastener of claim 2 wherein the connecting member (14) is flexible permitting another one of the first and second members to be next to the one of the first and second members when the one of the first and second members is on the tissue piercing deployment wire.

Regarding Claim 4, Hart teaches the fastener of claim 2 wherein the pointed tip is conical (101).

Regarding Claim 5, Hart teaches the fastener of claim 2 wherein the pointed tip comprises a sectioned portion (101).

Regarding Claim 6, Hart teaches the fastener of claim 2 wherein the pointed tip (101) is a dilation tip.

Regarding Claim 7, Hart teaches the fastener of claim 1 wherein the through channel comprises a through bore (83).

Regarding Claim 14, Hart teaches the fastener of claim 1 wherein the length of the connecting member (14) between the first and second members is adjustable.

Regarding Claim 47, Hart teaches a fastener assembly for use in a mammalian body, comprising: a fastener including a first member (12), a second member (16), wherein the first and second members have first and second ends, and a connecting member (14) fixed to each of the first and second members intermediate the first and second ends and extending between the first and second members, wherein the first and second members are separated by the connecting member (fig. 4), and wherein one of the first and second members has a longitudinal axis, a through channel (83) along the axis, and an elongated slot (103) communicating with the through channel; a deployment wire (54) arranged to be slidably received by the through channel of the one of the first and second members (fig. 9) and to pierce into the tissue (fig. 1) and arranged to be received by the elongated slot (103) during retraction of the deployment wire to enable early deployment of the one of the first and second members and reduced tissue compression; and a pusher (65) that pushes the one of first and second members into the tissue while on the deployment wire (fig. 2).

Regarding Claim 48, Hart teaches the assembly of claim 47 wherein the pusher (65) is also arranged to be slidably received on the deployment wire (54).

Regarding Claim 50, Hart teaches the assembly of claim 47 wherein the first and second members (12, 16) are arranged to be side by side when the one of the first and second members is slidably received on the deployment wire (it is noted that the two members are capable of being arranged side by side at any time).

Regarding Claim 51, Hart teaches the assembly of claim 47 wherein one end of the one of the first and second members (12) of the fastener further includes a pointed tip (101).

Regarding Claim 52, Hart teaches the assembly of claim 51 wherein the pointed tip comprises a truncated cone (101).

Regarding Claim 53, Hart teaches the fastener of claim 51 wherein the pointed tip comprises a sectioned portion (101).

Regarding Claim 54, Hart teaches the assembly of claim 47 wherein the through channel of the fastener comprises a through bore.

Regarding Claim 63, Hart teaches the assembly of claim 47 wherein the first member (12), the second member (16), and the connecting member (14) of the fastener comprises separate pieces.

Regarding Claim 64, Hart teaches the assembly of claim 47 wherein one end of the one of the first and second members (12) of the fastener further includes a dilation tip (101).

Regarding Claim 65, Hart teaches the assembly of claim 64 wherein the dilation tip is a pointed tip (101).

Regarding Claim 66, Hart teaches the assembly of claim 65 wherein the pointed tip of the fastener is conical (101).

Regarding Claim 67, Hart teaches the assembly of claim 47 wherein the through channel of the fastener comprises a through bore (83).

Regarding Claim 76, Hart teaches the assembly of claim 47 wherein the connecting member (14) of the fastener has a vertical dimension and a horizontal dimension transverse to the vertical dimension, and wherein the horizontal dimension is substantially less than the vertical dimension rendering the connecting member readily bendable in a horizontal plane.

Claims 1, 8, 11, 12, 16, 17, 21, 32-38, 47, 55, 58, 59, 60, 68, 78-84, 89, 90 are rejected under 35 U.S.C. 102(b) as being anticipated by Frazier et al. (US 6419669). Regarding Claims 1 and 47, Frazier teaches a fastener for use in a mammalian body, comprising: a first member (130); a second member (132), the first and second members having first (142) and second (146) ends; and a connecting member (92) fixed to each of the first and second members intermediate the first and second ends and extending between the first and second members (fig. 18), the first and second members being separated by the connecting member, and one of the first and second members having a longitudinal axis, a through channel (134) along the axis arranged to be slidably received on a tissue piercing deployment wire (96), and an elongated slot (portion between ends 140 and 142) communicating with the through channel and dimensioned to receive the tissue piercing deployment wire (96) and a pusher (150) that pushes the one of first and second members into the tissue while on the deployment wire.

Regarding Claims 8, 21, 55 and 68, Frazier teaches the fastener of claims 1, 16, 17 and 47 wherein both the first and second members include a longitudinal axis and a through channel along each respective axis (fig. 18).

Regarding Claim 11 and 58, Frazier teaches the fastener of claims 8 and 55 wherein the through channels are through bores.

Regarding Claims 12 and 59, Frazier teaches the fastener of claims 8 and 55 wherein the through channels are arranged to be slidably received by the tissue piercing deployment wire (fig. 19) and wherein the connecting member is flexible permitting the first and second members to be in line with each other on the tissue piercing deployment wire (it is noted that the connecting member meets the limitation allowing the first and second members to be in line with each other on the deployment wire as seen in figure 19, and as such in this case are considered flexible).

Regarding Claim 16, Frazier teaches the fastener of claim 1, wherein the first member, the second member and the connecting member all formed of plastic material (Column 15, proximal lines 55-60)

Regarding Claims 17, 32 and 78, Frazier teaches the fastener of claims 1, 16 and 47 wherein the first member, the second member, and the connecting member are integrally formed from a same tubular member stock (Column 15, proximal lines 55-60).

Regarding Claims 33 and 79, Frazier teaches the fastener of claims 32 and 78 wherein both the first and second members include a through channel for being slidably received in line on the tissue piercing deployment wire (fig. 19).

Regarding Claims 34 and 80, Frazier teaches the fastener of claims 32 and 47 wherein the fastener is formed of metal (Column 15, proximal lines 55-60).

Regarding Claim 35, Frazier teaches the fastener of claim 33 wherein the fastener is formed of a shape memory material (Column 15, proximal lines 55-60) and wherein the first and second members are self-deployable.

Regarding Claim 36, Frazier teaches the fastener of claim 35 wherein the fastener is formed of nitinol (Column 15, proximal lines 55-60).

Regarding Claims 37 and 83, Frazier teaches the fastener of claims 33 and 79 wherein at least one of the first and second members is self-deployable while on the tissue piercing deployment wire (Column 15, proximal lines 55-60).

Regarding Claims 38 and 84, Frazier teaches the fastener of claims 33 and 79 wherein at least one of the first and second members is self-deployable upon removal from the tissue piercing deployment wire (Column 15, proximal lines 55-60).

Regarding claims 44-46, 81-82, 89 and 90, Frazier teaches the fastener of claim 1 and 47 wherein the fastener is formed of a self deployable shape metal memory material such as nitinol (Column 15, proximal lines 55-60).

Regarding Claim 60, Frazier teaches the assembly of claim 59 further comprising a guide tube (52) extending over the deployment wire and the fastener.

Claims 99-102 and 106-109 are rejected under 35 U.S.C. 102(e) as being anticipated by DeVries et al. (US 7083630).

Regarding Claims 99 and 106, DeVries teaches a transoral gastroesophageal flap valve restoration tissue fixation assembly comprising: longitudinal member (20), a portion of which is arranged for transoral placement into a stomach, a fastener (200), and a tissue shaper (20) carried on the longitudinal member that shapes stomach tissue

Art Unit: 3731

into a shape, the tissue shaper comprising a pair of hingedly coupled first (21) and second (25) arms for receiving the tissue therebetween, the first arm including a fastener director that directs the fastener into the tissue and the second arm including an opening (26) permitting the fastener to be driven through the tissue while being held between the first and second arms.

Regarding Claims 100 and 107, DeVries teaches the assembly of claims 99 and 106 wherein the second arm (25) is a frame structure.

Regarding Claims 101 and 108, DeVries teaches the assembly of claims 99 and 106 further comprising a tissue gripper (28) that grips the tissue and pulls the tissue into and between the first and second arms.

Regarding Claims 102 and 109, DeVries teaches the assembly of claims 99 and 106 wherein the first arm has a tissue engaging surface and wherein the fastener director includes a channel (14) communicating with the tissue engaging surface through which the fastener passes into the tissue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-20, 27, 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hart in view of Sgro et al. (US 20050004575).

Hart teaches all elements of preceding dependent claims 1 and 47, and further teaches the following as described previously:

- one end of the one of the first and second members further includes a pointed tip.
- wherein the pointed tip comprises a truncated cone.
- wherein the through channel comprises a through bore.
- wherein the connecting member has a vertical dimension and a horizontal dimension transverse to the vertical dimension, and wherein the horizontal dimension is substantially less than the vertical dimension rendering the connecting member readily bendable in a horizontal plane.

but fails to teach wherein the first member, the second member, and the connecting member are all formed of plastic material, and the second member, and the connecting member are all formed in one piece. Sgro teaches a fastener wherein the device is formed of a single molded plastic, which aids in reducing cost of manufacture and ease

Art Unit: 3731

of manufacture. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Hart with a single molded piece of plastic as taught by Sgro in order to reduce cost of manufacture and ease of manufacture.

Claims 15, 24, 49 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hart or the combination of Hart and Sgro and further in view of Makower et al. (US 6491707). Hart and the combination of Hart and Sgro teach all elements of preceding dependent claims 1, 16 and 47, and further teaches wherein the fastening members are formed of plastic (Hart, Column 6, proximate lines 42-46), but fails to specify a material for the connector member and a guide tube extending over the deployment wire and the fastener, the other one of the first and second members being disposed next to the one of the first and second members within the guide tube.

Regarding the connector material, Makower teaches a fastener wherein the connector member is formed of elastic plastic in order to pull or draw the first and second members inwardly toward a common central point or location. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Hart or the combination of Hart and Sgro with an elastic plastic material for the connector member in order to pull or draw the first and second members inwardly toward a common central point or location.

Regarding the guide tube, Makower teaches a guide tube (26) extending over the deployment wire and the fastener, the other one of the first and second members being disposed next to the one of the first and second members within the guide tube (Column

Art Unit: 3731

10, proximate lines 33-48) in order to aid in using the device for intraluminal applications. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Hart or the combination of Hart and Sgro with the guide tube of Makower in order to aid in using the device for intraluminal applications.

Claims 25, 30, 31 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hart the combination of Hart and Makower, and the combination of Hart, Sgro and Makower and further as a matter of design choice. Hart, the combination of Hart and Makower and the combination of Hart, Sgro and Makower teach all limitations of preceding dependent claims 1, 16 and 47 as previously described, but fail to teach wherein the connecting member is formed of a plastic, permanently deformable material, and wherein the two members are formed of different textured materials. It would have been an obvious matter of design choice to modify Hart, the combination of Hart and Makower, and the combination of Hart, Sgro and Makower with a plastic connector of, permanently deformable material and the fastening members of different textured materials, since applicant has not disclosed that such a material provides any advantage over an elastic material, and it appears that Hart, the combination of Hart and Makower, and the combination of Hart, Sgro and Makower perform the task of fastening tissue equally well as that of the application.

Claims 26 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Hart and Sgro as applied to claims 1, 16, 47 and 61 above, and further in view of Suzuki et al. (US 20030216613).

Hart and the combination of Hart and Sgro teach all limitations of preceding dependent claims 1, 16, 47 and 61 but fail to teach device includes a color pigment contrasting with body tissue color to enable visualization of the fastener with an endoscope. Suzuki teaches a surgical implant wherein the device has a color which can be recognized in an endoscopic image in the body cavity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Hart and the combination of Hart and Sgro as taught by Suzuki in order to recognize the device in an endoscopic image in the body cavity.

Claims 9, 22, 56, 10, 23, 57, 69 and 70 rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier in view of Hart and further as a matter of design choice. Frazier teaches all limitations of preceding dependent claims 1, 8, 16, 17, 47 and 68, but fails to teach wherein one end of both the first and second members include pointed dilation tips in opposite directions. Hart teaches a device wherein one of the members includes a pointed tip for aiding in advancing the device through tissue. It would have been an obvious matter of design choice to provide the device of Frazier with both the first and second members including pointed tips in opposite directions since applicant has not stated that such a configuration provides any advantage and it appears that the combination of Hart and Frazier performs the task of advancing the device through tissue equally well as that of the application, and further it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. .

Claims 29 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hart as a matter of design choice. Hart teaches all limitations of preceding dependent claims 1 and 47, but fails to teach a plurality of connecting members extending between the first and second members, and wherein a plurality of the fasteners slidingly received on the deployment wire. It would have been an obvious matter of design choice to provide Hart with plural connecting members and fasteners on the deployment wire since applicant has not stated that providing more than one connector provides any advantage, and it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 72 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Hart and Makower, and further as a matter of design choice. The combination of Hart and Makower teaches all limitations of preceding dependent claims 47, 71 and 73 as previously described, but fails to teach wherein the connecting member of the fastener is formed of one of polyurethane, thermoplastic elastomer, polyethylene and polypropylene. It would have been an obvious matter of design choice to denote the material as one of the above listed since applicant has not stated that these materials provide any advantage over another plastic elastic material and it appears that the combination of Hart and Makower performs the task of providing an elastic connection member equally well as that of the application, and further it has been held to be within the general skill of a worker in the art to select a known material

Art Unit: 3731

on the basis of its suitability for the intended use as a matter of obvious design choice.

In re Leshin, 125 USPQ 416.

Claims 95-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hart in view of Makower, and further as a matter of design choice. Hart teaches all limitations of preceding dependent claim 47, but fails to teach the following:

- a guide tube extending over the deployment wire and fastener and wherein the guide tube includes a distal notch permitting a proximal one of the first and second members to deploy before the guide tube proximally clears the proximal member.
- wherein the proximal one of the first and second members is deployable while on the deployment wire
- wherein the deployment wire includes a bent tip

Makower teaches a tissue fastening device wherein a guide tube (28) extends over the deployment wire having a bent tip (32, fig. 10) and fastener (28) and wherein the guide tube includes a distal notch (28b) and wherein the proximal one of the first and second members is deployable while on the deployment wire (fig. 10), in order to aid in placement of the device and to allow a proximal one of the first and second members to deploy before the guide completely releases the fastener. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Hart as taught by Makower in order to aid in placement of the fastener and allow a proximal one of the first and second members to deploy before the guide completely releases the fastener.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hart in view of Cragg (US 6315789). Hart teaches all limitations of preceding dependent claim 1, but fails to teach wherein the fastener is at least partially radio opaque. Cragg teaches a medical fastener wherein the fastener is at least partially radio opaque in order to be able to view the device using medical imaging techniques to determine the device has been placed at the proper location. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Hart with a radiopaque material as taught by Cragg in order to be able to view the device using medical imaging techniques to determine the device has been placed at the proper location.

Claims 39, 40, and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier as a matter of design choice. Frazier teaches all limitations of preceding dependent claims 1, 32, 33, 38, 47, 78, 79 and 84, but fails to teach a crimp on one of the members. Frazier does teach wherein the device is slidably retained on the deployment wire. It would have been obvious to one of ordinary skill in the art to provide a crimp in the device since it is well known that adding an area of decreased cross sectional area will provide a tighter fit on a deployment wire.

Claims 103 and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries as a matter of design choice. DeVries teaches the assembly of claim 99, 102, 106 and 109 as previously described, but fails to teach wherein the fastener director includes a plurality of the channels to direct a like plurality of fasteners into the tissue. It would have been an obvious matter of design choice to provide a plurality of

Art Unit: 3731

channels since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193

USPQ 8

Claims 104, 105 and 111-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Vries in view of Cope (US 6699236) and further in view of Laufer et al. (US 6835200). Devries teaches all limitations of preceding dependent claims 99, 102, 106 and 109, and further teaches the following:

- a fastener deployment wire (120) extending through the channel and that guides the fastener through the channel and into the stomach tissue.
- the fastener (220) comprises a first member, a second member, the first and second members having first and second ends, and a connecting member (205) fixed to each of the first and second members intermediate the first and second ends and extending between the first and second members, the first and second members being substantially parallel to each other and separated by the connecting member when the fastener is deployed (fig. 49)

DeVries fails to teach wherein one of the first and second members having a longitudinal axis and a through channel along the axis arranged to be slidably received on the fastener deployment wire. Cope teaches a tissue fastener device wherein wherein one of the first and second members having a longitudinal axis and a through channel along the axis arranged to be slidably received on the fastener deployment wire (fig. 9) in order to allow a cannula to pass through the fastener. It would have been obvious to one of ordinary skill in the art at the time the invention was made to

Art Unit: 3731

modify the device of DeVries as taught by Cope in order to allow a cannula to pass through the fastener.

The combination of DeVries and Cope fails to teach a tissue gripper including a helical coil that grips the stomach tissue and pulls the stomach tissue into and between the first and second arms. Laufer teaches a tissue fastening device wherein a coil (20) pulls the stomach tissue between the arms of the gripping device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of DeVries and Cope with a coil as taught by Laufer in order to aid in pulling the stomach tissue between the arms of the gripping device.

Allowable Subject Matter

Claims 28, 41-43, 77, 86-88, 91-94 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Art Unit: 3731

Claims 1-5, 15, 16, 17, 18, 19, 20, 24, 25, 26, 30, 34-38, 44-54, 60-62, 67, 71, 73, 80-84, 89, 90 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-36 of copending Application No. 10/949/737. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP

8/14/06


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

8/20/06